

## APPENDIX A

### PATENT

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentee:	Barry M. Tydings	Examiner:	Jerry D. Johnson
Reexam Control No.:	90/007,813	Group Art Unit:	3991
Patent No.:	6,805,837	Docket No.:	56990-010600
Issued:	October 19, 2004	Confirmation No.:	4405
Customer No.:	33717		
Title:	ASSAYING DEVICE AND METHOD FOR IN FIELD URINALYSIS		

#### CERTIFICATE UNDER 37 CFR 1.6(d)

I hereby certify that this correspondence and identified enclosures are being transmitted via facsimile only to the Central Reexam Unit at Facsimile No. (571) 273-9900, and Supervisory Patent Examiner Deborah D. Jones at Facsimile No. (571) 273-1535 on August 9, 2007.

  
Name: Kelly Simpson

#### **THIRD SUPPLEMENTAL DECLARATION OF BARRY TYDINGS IN SUPPORT OF PATENTABILITY OF CLAIMS OVER THE CLAIMS OF PATENT NO. 6,379,620**

I, Barry Tydings, declare as follows:

1. I am the inventor in respect of the above application.
2. The claims of Patent No. 6,379,620 (the "620 patent") relate to an assay where the wicking extended from one side of a backing over the top of a backing and down the other side of the backing.
3. With the wick system of the claims of the '620 patent we experienced problems with wicking, migration and flooding of urine on the wick and the assay strip. If there was too much urine in the cup, the urine on the wicking would flood the assay strip. This would wipe out the antibodies and antigens on the assay strip, which negated the test. If there was not enough urine in the cup, the urine would be insufficient to wick over the top and therefore would not activate the assay test strip. Either way there was no consistent migration of the urine to the

wicking and the test strips. The test cups with this technology are not scientifically or technically consistent to provide for acceptable testing.

4. The technology of the claims of the present application are directed to an invention which avoids these problems with wicking over the top of the backing, namely the subject of the claims of the '620 patent. The claims of the present application represent an important advance scientifically and technically over the technology of the claims of the '620 patent, since they cover an assay where the urine flow is contrary to having the urine flow with the wicking extending over the top.

5. I consider myself a person having ordinary skill in the art of urine drug testing cups. I have been involved in the design, manufacture and sales of cups for this purpose since 1998. I am also aware of the demands of the design community and present in the marketplace of such cups. This has been my main business during all that time. Over this time I have designed, had manufactured and sold over 4,000,000 different kinds of cups, essentially most of which are the cups of the present claims where there is no wicking of urine over the top of the backing. I have customers throughout the United States and also many other countries. These cups as covered in the claims of the present patent have the urine wick solely up the wicking, or up the assay strip. In either case there is not a wicking of urine over the top of the backing (as per the claims of the '620 patent). I know that the cups of the present application are far superior to those of the '620 patent for the reasons stated above.

6. For design and manufacture I have traveled to different countries to ensure the highest standards, and I believe I know most of the nuances associated with the effective design and manufacture of such cups.

7. I consider that there are many infringers of cups bearing the structure and functional characteristics of the claims of the present application. I have pending patent infringement litigation against Acon, a manufacturer of cups which I consider as violating my patent rights. Such litigation is currently stayed because of the reexamination of my patent in this application. From market information that I have obtained I know that many hundreds of thousands of such infringing cups are continuing to be sold. This commercial reality, when considered as additive to my own high volumes of cups reaffirms that the technology of the not-

over-the-top wicking structure and function is patentably different from the over-the-top wicking structure of the '620 patent. I am unaware of any commercial cups in the market anywhere that uses the '620 over-the-top wicking, and this could be due the technical and functional inferiority of such a system as described above.

8. In view of my experience in the field of such assays, I believe that changing the construction from over-the-top wick construction to the construction of wicking up the wick and up the strip was not an obvious change.

9. Prior to my inventing the up the wick/up the strip construction, there were no competitors in this field. After this up the wick/up the strip construction was developed, many competitors entered the field, because at that time I had developed a new and non-obvious construction which worked effectively and for which there was a substantial commercial demand, and this invented construction solved the previously unsolved need.

10. My up the wick/up the strip construction of urine test cup is an important advance which took ingenuity. It was not merely a substitution of alternatives, or an expected result. Before I thought of this "up the wick/up the strip" construction, I had tried many different techniques to create a stable consistent product with the over the top wicking. I did not remotely even think of the reverse construction, namely the "up the wick/up the strip" construction would obviate all the prior problems. Simply stated, it was not an obvious solution.

11. I was forced to abandon the wicking over the top construction after many trials, experiments and efforts to increase its stability and reliability, none of which worked.

12. It was not readily obvious to me at that time, that the up the wick/up the strip construction could work, and solve the problems being experienced with the wicking over the top construction. It would not have been obvious to anyone of skill in the art at the time and who was actually struggling with the real problems of making a workable reliable product, that this totally different construction would actually work and solve those problems.

13. The up the strip wicking functions differently from a down the wick flow of urine, which was a characteristic of the over the top wicking construction. It would not have been obvious to make the change of flow and appreciate that it would function.

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14. I consider that the up the wick/up the strip construction would not have been obvious at the time in the light of my prior over the top wick construction. It would have taken ingenuity to achieve the successful urine cup testing system with the up the wick/up the strip construction.

All statements made herein of my own knowledge are true, all statements made hereon information and belief are believed to be true, and further these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under U.S.C. 1001, and may jeopardize the validity of the application of any patent issuing thereon.

Dated:

Aug 9, 2007

Barry Tydings  
BARRY TYDINGS